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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,447	09/08/2003	Timothy Crowley	9138-0098US	4731
28529 GALLAGHER	7590 08/28/2007		EXAMINER	
GALLAGHER & KENNEDY, P. A. 2575 E. CAMELBACK RD. #1100			MENON, KRISHNAN S	
PHOENIX, AZ	2 85016		ART UNIT PAPER NUMBER	
			1723	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/658,447	CROWLEY ET AL.				
Office Action Summary	Examiner	Art Unit				
	Krishnan S. Menon	1723				
The MAILING DATE of this communication ap Period for Reply	pears on the cover sheet with	the correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION  - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, erectified. If NO period for reply is specified above, the maximum statutory, period Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	136(a). In no event, however, may a repoly within the statutory minimum of thirty I will apply and will expire SIX (6) MONTI te, cause the application to become ABA	ly be timely filed  (30) days will be considered timely.  HS from the mailing date of this communication.  NDONED (35 U.S.C. § 133).	٠			
Status		•				
1) Responsive to communication(s) filed on 16	August 2007.	•				
	is action is non-final.					
3) Since this application is in condition for allows		s, prosecution as to the merits is				
closed in accordance with the practice under	•	·				
Disposition of Claims						
4)⊠ Claim(s) <u>1 and 3-110</u> is/are pending in the ap	polication.					
	4a) Of the above claim(s) <u>1-6,13-64 and 69-71</u> is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.	_	•				
6)⊠ Claim(s) <u>7-12,65-68 and 72-110</u> is/are rejected						
7) Claim(s) is/are objected to.	-0-					
8) Claim(s) are subject to restriction and/	or election requirement.					
Application Papers		·				
9) The specification is objected to by the Examin	ner					
10) The drawing(s) filed on is/are: a) ac		v the Examiner				
Applicant may not request that any objection to the	· · · · ·					
Replacement drawing sheet(s) including the corre						
11) The oath or declaration is objected to by the E						
Priority under 35 U.S.C. § 119						
		140(-) (d) -= (5)				
<ul><li>12) Acknowledgment is made of a claim for foreig</li><li>a) All b) Some * c) None of:</li></ul>	n priority under 35 U.S.C. §	119(a)-(d) or (f).				
1. Certified copies of the priority documer	1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documer	nts have been received in Ap	plication No				
<ol><li>Copies of the certified copies of the pri</li></ol>	ority documents have been r	eceived in this National Stage				
application from the International Bure	au (PCT Rule 17.2(a)).					
* See the attached detailed Office action for a lis	st of the certified copies not re	eceived.				
Attachment(s)						
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> </ol>		mmary (PTO-413) 'Mail Date				
<ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date</li> </ul>		ormal Patent Application (PTO-152)				

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### **DETAILED ACTION**

Claims 1 and 3-110 are pending after the amendment of 11/4/05, of which claims 1-6,13-64, 69-71 are withdrawn from consideration, as of the RCE of 2/1/07.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 7-10, 65-68,72-83, 85,87-92,97-105 and 107-110 are rejected under 35
   U.S.C. 102(b) as being anticipated by Sundberg et al (US 6,090,251).

Sundberg teaches a microfluidic instrument in figure 7 comprising an input (70), a first passage (76), a tangential filter in the first passage (the first of the filter 90, which is a weir type filter – see figure 8), and multiple liquid flow paths (78) downstream of the filter as claimed – for claim 7, the second and third flow paths (78) are downstream and is tangentially past the first filter (90). For claim 81, all channels 78 are downstream, because claim 81 does not recite "tangential" structure. Figure 7 shows only three channels 78, but the abstract and column 4 lines 3-10 teaches that any number of channels 78 are possible (such as five or more). All flow paths are parallel, lead to an output (82,84), have analytical provisions (column 1 lines 10-15, column 5 lines 15-28), and have capillary action (abstract). Tangential flow as in claim 85 over filter 90.

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Claims 65-68, 98 recite the means plus function language for continuous flow, which is capillary action as disclosed in the specification (35 USC 112, sixth paragraph, means plus function language would be the corresponding disclosure or equivalents thereof). Sundberg teaches the structure recited in the claims as above.

Claim 87, 104: smooth surface, semiconductor – see materials in column 6 lines 57-67.

Claim 88, 101: several instruments, part of a device – see abstracts: microfluidic substrates; column 1 lines 5-10 describe the invention as structure for introduction of fluids into devices.

Claim 92: covering plate – see figures 7 and 8: plan and cross-sectional elevation, showing covered structures.

Claim 97: weir type opening – see figure 8.

Claim 72-80, 82,83, 89,90, 99,100, 107-110: the recitations in these claims, 'the complex fluid', blood, cell lysis, the flow times, filtrate quantities, and other 'instrument requirements' are intended use, which are not patentable. The instrument taught by the reference is capable of all these. See also column 9 lines 50-67.

Claim 102, 105: multiple receiving means – see 70, figure 7.

Response to arguments traversing this rejection: Applicant's argument that Sundberg's region 90 in figures 7-9 is not a filter, but only a limit region acting as a liquid mixing barrier is not convincing. Applicant's recited structure is a tangential weir filter, wherein the "filter" is a weir of shallower depth than that of the adjacent channels. The reference teaches exactly the same structure, and therefore, anticipates the claims.

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The reference may be teaching an intended use of the weir 90 as a barrier between two different liquids 86 and 92, but that would be only intended use. Reference anticipates the claims because of the structure. The other argument applicant submits is that the channels of the reference would fail to provide expanded flow path that drives tangential flow past a filter element by capillary action. Applicant's argument about this "expanded flow path" is not clearly understood, because figure 7-9 of the reference teaches flow paths 76 and 78 as expanded, when compared to the weir 90. Compare this with applicant's figures 1 and 2: channels 26 and 29 are expanded compared to weir 28. With respect to "capillary action", Sundberg repeatedly teaches that flow in the channels is by wicking. It is well known principle in fluid mechanics that wicking happens by capillary action. The free online dictionary defines **wick** as:

A piece of material that conveys liquid by capillary action.

tr. & intr.v. wicked (wikt), wicking, wicks

To convey or be conveyed by capillary action: water gradually wicking up through the bricks.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 11,12, 84,86,93-96 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sundberg as applied to claims 10 and 81 above, and further in view of Quake et al (US 2004/0248167).

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The teaching of Sundberg differs from claims 11 and 12 in the recitation of the details of the electro-optical means. Quake teaches a laser-optic detection system (figures, abstract, col 7 lines 50-59). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Quake in the teaching of Sundberg as one of the various intended uses of the Sundberg system for sample separation and analysis.

Claims 84,86,93-96 and 106 differ from the teaching of Sundberg in the recitation of certain dimensions of the channels. However, Sundberg teaches how to size the channels and optimize the instrument in column 9 line 50-column 10 line 38. Moreover, In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. Also, Sundberg teaches channel widths, etc., in column 6 lines 9-25 with respect to the generation of capillary action. Sundberg does not teach the length of the channels. Quake teaches the length of the channels as about 1  $\mu$ m to 2 cm, depending on the need for the analytical methods (see paragraph 187). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Quake in the teaching of Sundberg for analysis of the samples of Sundberg as taught by Quake.

Arguments traversing this rejection are addressed in rejection 1 above.

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3. Claims 81-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brody (US 5,922,210) in view of Quake et al (US 2004/0248167).

Brody teaches an instrument comprising an input (1-figures), filter (5), passages from input to filter (4) and filter to output (6) all of which are capillary flow paths (inherent), and liquids flow by capillary action (inherent). Material is silicon wafers (example). Channel dimensions, separated particle sizes and fluid volumes – see column 3 lines 50-67, column 5 lines 4-25 and col 6 lines 13-25. the fluid to be treated, such as blood, and residence times (15 seconds), are intended use.

Instant claims add the further limitation of plurality of fluid flow paths connected to the first passage to receive flow thereform by capillary action and channel dimensions, which Brody does not teach. Quake teaches plurality of capillary flow paths (32) from a reservoir (48) see - figure 1. which lead to an analyzer (50), and electro-optical means for testing (abstract); and channel dimensions such as length, width, etc in paragraph 153 and 187. It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Quake in the teaching of Brody for the analysis of the filtered samples as taught by Brody for analysis such as DNA detection, etc as taught by Quake. One of ordinary skill in the art would also use the teaching of Brody to pre-filter the samples of Quake as taught by Brody for removing unwanted particulates.

Response to arguments traversing this rejection:

Applicant argues:

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"As previously acknowledged by the Examiner Brody fails to teach or suggest a device that uses an expanded flow path or plurality of liquid flow channels to achieve a continuous flow mode".

This interpretation of the rejection is not accurate. The rejection only stated that Brody does not teach 'plurality of fluid flow paths' and 'channel dimensions'.

Argument, "therefore, it follows that the device of Brody requires and [sic] applied head pressure to achieve continuous flow", has no basis. Capillary flow in the channels of Brody is inherent. Applicant has not provided any evidence to contradict the inherency. Argument that the resulting combination would still fail to render the claimed invention obvious is also unsubstantiated.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krishnan S Menon

Primary Examiner

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